



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,516	08/20/2003	Steven K. MacLeod	01288/2/US	5971
26648	7590	10/20/2005	EXAMINER	
PHARMACIA CORPORATION GLOBAL PATENT DEPARTMENT POST OFFICE BOX 1027 ST. LOUIS, MO 63006			DEAK, LESLIE R	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/644,516

Applicant(s)

MACLEOD, STEVEN K.

Examiner

Leslie R. Deak

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 August 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/6/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 4 contains the trademark/trade name Act-O-Vial. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982).

The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a particular type of vial and, accordingly, the identification/description is indefinite.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the aqueous medium

Art Unit: 3761

of claim 1 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,089,432 to Crankshaw et al. Crankshaw discloses the invention substantially as claimed in the specification and the figures.

In particular, Crankshaw discloses the structure of a vial 11 with two chambers 13, 14 a stopper 17 intermediate the chambers, and an upper stopper 23. Crankshaw discloses that movement of the upper stopper is an actuating means that pushes the intermediate stopper out of its seal with the constricted portion 16 of the vial, allowing the contents of the two chambers to mix within the combined volume of the two chambers. Crankshaw further discloses the cap 44 over the top of the stopper, a thin wall of the stopper for needle piercing, and the connections, sleeves, and locks of the claimed vial (see, generally, columns 2-4).

Crankshaw fails to disclose that the upper chamber is filled with an aqueous medium and the lower chamber is filled with a gaseous medium. Crankshaw does teach, however, that the purpose of the two-compartment vial is to provide a stable storage solution wherein two substances, which may include a medication, may be stored completely independently from one another. Such independent storage is used when the combination of the substances in the first and second vials reduces the stability and shelf life of the combined solution or medicine. Crankshaw discloses that in a preferred embodiment, the upper compartment is filled with a powdered medication and the lower chamber is filled with a solvent. However, Crankshaw specifically discloses that the preferred embodiment is only one utilization of the invention, thereby contemplating other solutions or compositions in the chambers of the vial (column 3,

Art Unit: 3761

lines 42-45). Furthermore, it has been held that a) the mere reversal of the essential working parts of a device involves routine skill in the art, and b) omission of an element and its function in a combination where the remaining elements perform the same function as before involves only routine skill in the art.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a medicament in solution in one chamber, separated from a dehydratory gaseous medium (absent any lyophilized medicament) in the other chamber, as claimed, since the separation of the two components until just before use improves the stability and the shelf life of the mixed solution, as taught by Crankshaw.

6. Claims 5-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,089,432 to Crankshaw et al in view of US 6,481,435 to Hochrainer et al.

Crankshaw discloses the device substantially as claimed with the exception of the contents and relative formulations of the medicament within the vessel.

Hochrainer discloses that steroids such as, for example, clobetasol and meprednisone, among others, are often packaged in two-chambered dispensing vials in suspensions for administration to a patient in various concentrations (see column 4, lines 5-12, 38-50, columns 5-6).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to supply the vial disclosed by Crankshaw with a desired medicament for a particular medical treatment, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability

Art Unit: 3761

for the intended use as a matter of obvious design choice. See MPEP 2144.07, citing *In re Leshin*, 125 USPQ 416. Applicant has not provided any evidence of unexpected results with regard to the storage or use of the particularly claimed medicament compositions. Accordingly, Hochrainer clearly shows the use of medication, as noted above, a person of ordinary skill in the art would recognize that medication having the particular material claimed would be used in the medicament storage and dispensing vial disclosed by Crankshaw, absent any showing of such new and unexpected results over the prior art.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

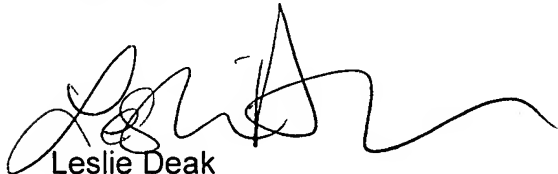
- a. US 3,087,638 Loper
 - i. Two-chambered mixing vial with intermediate stopper
- b. JP 2004337318 A Kawakami et al
 - ii. Steroid packaging system with steroid packaged independently of mixing area

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

Art Unit: 3761

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Leslie Deak', with a long horizontal flourish extending to the right.

Leslie Deak
Patent Examiner
Art Unit 3761
12 October 2005